

# UNITED STATES PATENT AND TRADEMARK OFFICE

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO
09/464,902	12/16/1999	WILLIAM C. OLSON	57906-AJPW/S 8227	
7	590 04/19/2006		EXAM	INER
COOPER & DUNHAM LLP			LE, EMILY M	
1185 AVENUE OF THE AMERICAS NEW YORK, NY 10036			ART UNIT	PAPER NUMBER
,			1648	

DATE MAILED: 04/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)			
	09/464,902	OLSON ET AL.			
Office Action Summary	Examiner	Art Unit			
	Emily Le	1648			
The MAILING DATE of this communication app Period for Reply	pears on the cover sheet with the c	orrespondence address			
A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA  - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period w  - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be tim vill apply and will expire SIX (6) MONTHS from , cause the application to become ABANDONEI	I. lely filed the mailing date of this communication. D (35 U.S.C. § 133).			
Status		•			
1) Responsive to communication(s) filed on 01/26	<u>6/2006+2/6/2006</u> .				
·=	This action is <b>FINAL</b> . 2b)⊠ This action is non-final.				
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is					
closed in accordance with the practice under E	x parte Quayle, 1935 C.D. 11, 45	3 O.G. 213.			
Disposition of Claims					
4)  Claim(s) 110-137 is/are pending in the applicat 4a) Of the above claim(s) is/are withdrav 5)  Claim(s) is/are allowed. 6)  Claim(s) 110-137 is/are rejected. 7)  Claim(s) is/are objected to. 8)  Claim(s) are subject to restriction and/or	vn from consideration.				
Application Papers					
9) The specification is objected to by the Examine 10) The drawing(s) filed on 16 December 1999 is/as  Applicant may not request that any objection to the Replacement drawing sheet(s) including the correct 11) The oath or declaration is objected to by the Ex	re: a) $\square$ accepted or b) $\boxtimes$ objector drawing(s) be held in abeyance. See ion is required if the drawing(s) is obj	e 37 CFR 1.85(a). ected to. See 37 CFR 1.121(d).			
Priority under 35 U.S.C. § 119					
12) Acknowledgment is made of a claim for foreign a) All b) Some * c) None of:  1. Certified copies of the priority documents 2. Certified copies of the priority documents 3. Copies of the certified copies of the prior application from the International Bureau * See the attached detailed Office action for a list of	s have been received. s have been received in Application rity documents have been receive u (PCT Rule 17.2(a)).	on No ed in this National Stage			
Attachment(s)					
<ol> <li>Notice of References Cited (PTO-892)</li> <li>Notice of Draftsperson's Patent Drawing Review (PTO-948)</li> <li>Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)</li> </ol>	·				
Paper No(s)/Mail Date	6)				

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## **DETAILED ACTION**

#### Status of Claims

Claims 1-109 are cancelled. Claims 110-137 are added. Claims 110-137 are 1. pending and under examination.

### Communication

2. The following office action is non-final to allow entry of rejection(s) that has not been entered in the record, along with new rejection(s) that is necessitated by Applicant's recent submission.

## **Drawings**

3. The drawings are objected to because a sequence identifier, SEQ ID NO:, is not provided for the sequence(s) disclosed in Figure 4. The Office notes that the sequences shown in Figure 4 are disclosed in the sequence listing submitted by Applicant as SEQ ID NOs: 1-4; however, in addition to the submission of a sequence listing, Applicant is required to amend Figure 4 to include a sequence identifier for each of the shown sequences, see MPEP § 2422.02 and 37 CFR 1.821(b).

Additionally, the drawings are further objected to because: In the instant, it is difficult to distinguish among the markings provided with Figure 4. It is noted that the markings represent three different levels of binding affinity, 0-25%, 26-50% and 51-75%, however, because the drawing is in black and white format, it is extremely difficult to distinguish among the markings.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate

prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

# Specification

4. The abstract of the disclosure is objected to because the inclusion of legal phraseology and undue length. Correction is required. See MPEP § 608.01(b).

Applicant is reminded of the proper content of an abstract of the disclosure: A patent abstract is a concise statement of the technical disclosure of the patent and should include that which is new in the art to which the invention pertains. If the patent is of a basic nature, the entire technical disclosure may be new in the art, and the abstract should be directed to the entire disclosure. If the patent is in the nature of an improvement in an old apparatus, process, product, or composition, the abstract should include the technical disclosure of the improvement. In certain patents, particularly those for compounds and compositions, wherein the process for making and/or the use thereof are not obvious, the abstract should set forth a process for making and/or use

thereof. If the new technical disclosure involves modifications or alternatives, the abstract should mention by way of example the preferred modification or alternative.

The abstract should not refer to purported merits or speculative applications of the invention and should not compare the invention with the prior art.

Additionally, Applicant is reminded of the proper language and format for an abstract of the disclosure: The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

# Claim Rejections - 35 USC § 112

- 5. The following is a quotation of the first paragraph of 35 U.S.C. 112:
  - The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
- 6. The rejection of claims 110-137 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement for reason(s) set forth in the previous office action is withdrawn in view of Applicant's 01/26/2006 amendment, wherein

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Applicant requires the second polypeptide to have and particular structure, whereby the structure, in combination with another polypeptide, binds to an epitope of CCR5.

- 7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

  The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
- 8. Claims 110-137 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are indefinite because of the following recitation, "wherein the polypeptide in combination with a polypeptide comprising a light chain of an anti-CCR5 antibody or a portion thereof containing three CDR regions". In the instant, the claims do not clearly set forth a distinction between the first polypeptide and a second polypeptide. For instance, claim 110 recites the terms "a polypeptide" and "the polypeptide" to refer back to a polypeptide comprising a heavy chain of an anti-CCR5 antibody or a portion thereof containing three CDR regions; however, claim 110 also recites the term "a polypeptide" to refer to a polypeptide comprising a light chain of an anti-CCR5 antibody or a portion thereof containing three CDR regions. In the instant, claim 110 refers to two distinct polypeptides by the same reference, a polypeptide.

Additionally, the claims are rendered indefinite for the following recitation: "wherein the three CDR regions comprise consecutive amino acids the sequences of which are identical to the sequences of CDR regions" present in the heavy/light chain of a monoclonal antibody. In the instant, the scope of the subject matter embraced by the cited recitation is unclear. For the purpose of examination, the Office presumes that

the cited recitation requires portion of the polypeptide to comprise three CDR regions, wherein the CDR regions is identical to the three CDR regions present in the heavy/light chain of a monoclonal antibody recited in the claims.

9. Claim 124 and 137 recite "each encoded polypeptide" in line 2 of the claims.

There is insufficient antecedent basis for this limitation in the claim. In the instant, the claims are solely directed to one encoded polypeptide, thus, it is evident that the recitation "each encoded polypeptide" lacks proper antecedent basis.

#### Conclusion

- 10. No claims are allowed in view of the pending rejection(s). However, a response properly addressing the objection(s) and rejection(s) presented herein would render the subject matter recited in claims 110-137 allowable. In the instant, the subject matter recited in claims 110-137 is free of the prior art.
- 11. Additionally, as a courtesy, the Office attempted to contact Ashton Delauney at 212 278 0400, on 04/03/2006, to communicate the content of the instant office action. However, telephonic connection to Ashton Delauney was not available at the cited telephone number.
- 12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Emily Le whose telephone number is (571) 272 0903. The examiner can normally be reached on Monday Friday, 8 am 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (571) 272-0902. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jeffrey S. Parkin, Ph.D. Primary Patent Examiner Art Unit 1648

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